

Chapter 6

A Framework for Designing and Evaluating Internet Interventions to Improve Tinnitus Care

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ABSTRACT

Tinnitus can be a debilitating hearing-related symptom. Access to evidence-based tinnitus interventions remain limited. Tele-audiology can assist by providing a clinically and cost-effective tinnitus management route. This chapter highlights how this is made possible by focusing on one form of tele-audiology, namely an internet-based intervention. Guidelines are provided for the development of such interventions. A framework outlining the various processes involved in evaluating newly developed interventions is also provided. The chapter closes by discussing factors that may facilitate or hamper the dissemination of new interventions into existing service delivery models. This well-defined outline for intervention development and evaluation can be applied and used to guide innovative intervention models by stakeholders.

DOI: 10.4018/978-1-5225-8191-8.ch006

INTRODUCTION

Technological advances can assist with the provision of healthcare interventions aimed at improving the health of individuals. Utilising these developments should be explored, especially when a chronic condition or symptom exists which may require multiple complex interventions and place a substantial burden on health organisations (West, 2012). Implementing novel interventions without a systematic process of careful development and evaluation may result in them failing to reach their full potential or produce the desired outcomes (Craig et. al., 2008). The aim of this chapter is to encourage utilisation of digital healthcare in the context of an auditory-related condition known as tinnitus. It provides a comprehensive and systematic framework for the design and evaluation of these interventions. The examples and well-defined guidelines can be applied by those interested in improving service delivery models such as clinicians, scientists, researchers, students, and government based workers.

This chapter was written by a diverse range of professionals, including a clinical psychologist, audiologist, a tinnitus expert, and academic-researchers, with a common interest in helping those with tinnitus. While working in clinical settings, each noticed some recurring themes surrounding barriers to providing the quality care patients required. Many stories of unmet needs and people desperate for help were heard. The authors, therefore, pioneered models to improve interventions, which will be shared in this chapter.

The objectives of this chapter are:

1. To outline the barriers to accessing tinnitus care in current tinnitus care models
2. To highlight how inclusion of tele-audiology can improve access to evidence-based intervention for tinnitus
3. To provide a framework for the development of Internet-based interventions
4. To outline the sequential procedures required for Intervention evaluation
5. To identify key processes that aid implementation of newly developed interventions

BACKGROUND

Tinnitus is often characterised by perceiving sounds such as ringing or buzzing in the absence of an identifiable external sound source (Baguley, Andersson, McFerran, and McKenna, 2013). As one of the most distressing and debilitating hearing-related symptoms, the effects can be devastating (Cima, Vlaeyen, Maes, Joore, and Anteunis, 2011). Whether emerging gradually or suddenly, the onset is frequently a significant life event and often associated with numerous challenges

and increased levels of stress (Scott et al., 2016). Those experiencing tinnitus may feel isolated, when in actual fact it is one of the most highly prevalent chronic auditory-related symptoms, affecting an estimated 10–15% of the adult population across the globe (Davis and Rafaie, 2000; Khedr et al., 2010; Michikawa et al., 2010; Shargorodsky, Curhan, and Farwell, 2010). This incidence is likely to continue to rise, due to factors such as an increase in life expectancy and recreational noise exposure (Martinez, Wallenhorst, McFerran, and Hall, 2015). Finding a cure that permanently abolishes tinnitus remains elusive due to the heterogeneous aetiology, varying individual experiences and limited understanding regarding the mechanisms and pathophysiology (Elgoyhen, Langguth, De Ridder, and Vanneste, 2015). This realisation of having to live with hearing these sounds all the time, together with the loss of silence, can result in a range of distressing emotional reactions. For those greatly troubled by tinnitus, associated adverse consequences may include insomnia, reduced concentration, anxiety, and depression which can impact both short and long term functioning (Hall et al., 2018; Langguth, 2011).

Individuals often feel helpless and unsure how to manage their tinnitus. Some withdraw and limit going to places they believe will worsen their tinnitus. This approach is often associated with greater distress and poorer long-term outcomes (Beukes et al., 2017a; Hayes, Wilson, Gifford, Follette, and Strosahl, 1996). Those with tinnitus often do not realise that there are ways to cope, despite having tinnitus. The ultimate goal during tinnitus interventions is to become accustomed to, i.e. habituating, to hearing the sounds. Habituation is the point where perceiving tinnitus no longer results in a negative emotional response and does not affect day-to-day functioning. Tinnitus interventions can aid habituation and help those living with tinnitus to overcome the devastating effects tinnitus can have. Ensuring that interventions are available for those with distressing tinnitus is, therefore, imperative.

RESTRICTIONS IN CURRENT TINNITUS CARE MODELS

Considering the distress often associated with tinnitus, appropriate clinical care pathways are crucial. Unfortunately, these are not always available due to obstacles preventing delivery of appropriate interventions. A clear understanding of these limitations is required prior to considering potential solutions to address them. The main restrictions include provision of evidence-based interventions, access to tinnitus care, and the costs associated with intervention delivery as outlined in the following sections.

Limited Provision of Evidence-Based Interventions

In terms of tinnitus management, a significant barrier is the lack of standardisation in the approaches used (Hoare, Kowalkowski, Lang and Hall, 2011). Moreover, there is a lack of evidence supporting the efficacy of many tinnitus management strategies (Landgrebe et al., 2012). What adds to the complexity of tinnitus is that tinnitus-related distress is not related to the loudness or character of tinnitus experienced, but rather to the psychological complaints thereof (Andersson, 2002). Tinnitus interventions targeting the tinnitus sound itself, are, therefore, often less effective than psychological interventions which focus on improving functionality and minimising the effects tinnitus may have (Hoare et al., 2011). The intervention with the most evidence in reducing tinnitus distress at present is cognitive behavioural therapy (CBT), a type of psychological therapy (Grewal, Spielmann, Jones, and Hussain, 2014; Hesser, Weise, Westin, and Andersson, 2011). Despite this evidence, there is limited provision of CBT in clinical practice, largely due to a shortage of trained professionals to provide CBT for tinnitus (Gander, Hoare, Collins, Smith, and Hall, 2011). Further discrepancies exist, in that the management routes most frequently offered to patients are often those with the least evidence of efficacy. Bhatt, Lin, and Bhattacharyya, (2016) for instance reported that doctors in the USA recommended medications 45% of the time opposed to cognitive behavioural therapy only 0.2% of the time. Hall et al. (2011) reported a similar trend with doctors in the USA, UK and Europe recommending pharmaceutical treatment for acute tinnitus 77% of the time and psychological interventions for chronic tinnitus 35% of the time.

Lack of Access to Speciality Care

Accessing specialised health services largely depends on geographic location, both within countries and in different countries where Audiology as a profession for instance does not exist. This may be related to a shortage of resources, increase in service-demand, lack of trained professionals, poor infrastructure and a focus on basic healthcare (Smith, McKeon, Blunt, and Edwards, 2014). The demand for these services may also lead to an increase in appointment waiting times which has been associated with poorer outcomes for a variety of health issues (Pizer and Prentice, 2011; Smith et al., 2014). Despite psychological treatment modalities having the best evidence base for successful tinnitus management, they may not be available as demonstrated by a survey performed in the UK (McFerran, Hoare, Carr, Ray, and Stockdale, 2018). For patients experiencing significant levels of health-related distress, such as those with chronic tinnitus, overcoming these barriers by maximising access to care and minimizing the waiting time for this care should be prioritised

(Gander et al., 2011). Service delivery models should focus on improving access to evidence-based care.

The Costs Associated With Intervention Delivery

Provision of healthcare cannot be considered without evidence of the cost-effectiveness of these interventions. As no cure has been identified, treating tinnitus remains challenging and costly at an estimated annual healthcare cost of £750 million and resulting societal cost of £2.7 billion per year in the UK (Stockdale et al., 2017). Due to its chronic nature, healthcare services are further pressurised as processes are often extensive and often encompass referrals to various disciplines to address hearing difficulties and possible indirect psychosocial effects (Cima et al., 2009). The incidence of tinnitus is likely to continue to rise, due to factors such as an increase in life expectancy and recreational noise exposure (Martinez et al., 2015) which may place further financial constraints on healthcare systems that are already pressurised. Innovative planning is required develop interventions that are able to meet these additional demands and challenges e.g. poor patient to health professional ratios.

Of importance is ensuring that these services are sustainable and meet the demands and challenges such as the poor patient to health professional ratio.

THE ROLE OF TELE-AUDIOLOGY FOR TINNITUS

The automation and transferability of telehealth provides unique opportunities to overcome barriers and improve healthcare options for numerous health-related difficulties (Polisena, Coyle, Coyle, and McGill, 2009; Totten et al., 2016). Telehealth encompasses a range of alternative formats of healthcare delivery such as use of the Internet, computer-based technologies, videoconferencing and smartphone applications. Due to the versatility of the Internet, many telehealth self-help interventions are Internet-based (Reavley and Jorm, 2011). The Internet has become a means for many people with tinnitus to connect, as is seen with the increasing specific online tinnitus forums and online support groups (Kaplan, Salzer, Solomon, Brusilovskiy, and Cousounis, 2011). Self-help tinnitus management is often advocated as a means of increasing an individual's knowledge of tinnitus (Nyenhuis, Golm, and Kröner-Herwig, 2013) and utilizing the Internet provides a means to enable self-help management. The Internet is also a familiar vehicle used widely by patients who seek information about health-related difficulties they face (Reavley and Jorm, 2011). This chapter will focus on one form of tele-audiology, namely Internet-interventions. Within this field there are various forms of tinnitus Internet-interventions, including educational resources such as the Tinnitus E-Programme (Greenwell, Featherstone,

and Hoare, 2015), those based on acceptance and commitment therapy (Hesser et al., 2011) or cognitive behavioural therapy (Andersson, Strömberg, Ström, and Lyttkens, 2002). This chapter will concentrate on cognitive behavioural therapy delivered on the Internet (iCBT) as it is the intervention with the greatest evidence-base and has been used in current healthcare models. These iCBT interventions have been shown to be effective for a range of difficulties, including auditory related problems (Thorén, Öberg, Wänström, Andersson, and Lunner, 2014), anxiety (Tulbure, 2011), mood disorders, depression (Johansson and Andersson, 2012) headache, insomnia, and somatic problems such as chronic pain (Arnberg, Linton, Hultcrantz, Heintz, and Jonsson, 2014; Cuijpers, van Straten, and Andersson, 2008; van Beugen et al., 2014). The principles discussed in this chapter are, however, transferable to other forms of tele-audiology.

When considering the role of any form of tele-audiology for tinnitus, it is important that it is seen as an additional intervention route, and not the only management route. Due to the heterogeneous nature of tinnitus, having a variety of management options to suit different needs is important. By nature of the intervention, those undertaking it need access to a computer, the Internet, and should have the ability to read, write and understand text. There will be people who do not have the available resources or language skills to undertake such interventions, and alternate management formats should be available to them.

The Potential of Tele-Audiology

An Internet-intervention has clear service delivery advantages, including widespread access to tinnitus services particularly in underserved communities, but the application is not restricted to those with reduced clinical access. It can also be accessed easily by those who may find attending hospitals difficult due to mobility issues, needing to take time off work, reliance on others for transport or poor health (Chiang, Chen, Dai, and Ho, 2012). Additional intervention routes ensure that distressed patients can be treated in a more timely manner, which, in turn, can reduce the anxiety and distress often associated with waiting for an intervention. Health professionals can also be freed up to see patients who require urgent care. Service delivery costs are always an important factor. A delivery model including an Internet intervention could be more cost-effective than face-to-face (F2F) interventions, as fewer resources are required (Hedman et al., 2014). The Internet is a viable alternative for people who are unable to access F2F care for reasons such as a long travelling time, the stigma of seeing a therapist, communication difficulties due to hearing impairment or other health-related problems that may make attending an appointment difficult (Cuijpers et al. 2008). Another advantage is the ability to access an intervention at home, at a comfortable pace and when individuals are in the right emotional

state to absorb new information (Griffiths and Christensen, 2007; Muñoz, 2010). Learning and retention can be facilitated as the information can be revised at any stage. (Ferguson and Henshaw, 2015), for instance, found improved knowledge of hearing aids for those patients who obtained information online as opposed to those only receiving instructions in a clinical setting. This mode of intervention may also suit those who find it hard speaking to someone F2F about personal problems due to reduced stigma and online anonymity (Griffiths, Lindenmeyer, Powell, Lowe, and Thorogood, 2006). Outcome monitoring can be embedded in the intervention, allowing closer monitoring of progress, easier data management and time-saving capabilities. It can improve efficiency in healthcare as interventions can be standardised regardless of the therapist or clinic attended. Changes in health care behaviours towards more self-management have been evident following the use of self-monitoring fitness and health-related apps and devices (Chiauzzi, Rodarte, and DasMahapatra, 2015). An Internet-based intervention can empower individuals to take responsibility and promote self-efficacy (Bendelin et al., 2011; Williams and Whitfield, 2001). Tele-audiology thus holds real potential for bridging barriers evident in healthcare provision.

A FRAMEWORK FOR DEVELOPING INTERNET-BASED INTERVENTIONS

The potential of tele-audiology will not be realised if interventions are not systematically developed and evaluated. The sections that follow are aimed at providing such a framework specifically for tele-audiology using the principles outlined for developing and evaluating complex interventions (those with a number of interacting components) provided by the medical research council (Craig et al., 2008). The process is lengthy, but all the stages are important. Neglect of any of these steps can make it less probable that the intervention will be implemented successfully. It is likely that the differences reported in efficacy and effectiveness of individual Internet-interventions are due to optimal designs for intervention development and evaluation not always been used (Morrison, Yardley, Powell, and Michie, 2012). This section is intended to highlight the key components that could improve outcomes and minimise barriers. The framework presented has largely been drawn from Andersson, Carlbring, Berger, Almlöv, and Cuijpers (2009) “What makes Internet therapy work?” article. Further insights from (Morrison et al., 2012) outlining design features leading to effective e-Health have also been incorporated. Guidelines for developing Internet-based interventions are presented below.

Suitable Functionality of the Internet-Intervention Platform

Internet interventions should ensure flexibility within the design in order to adapt to technological advances and the progression of new knowledge. At present these include ensuring the page layout is fully responsive, transparently adapting to screen size and ensuring a fully functional experience regardless of whether the platform is accessed using a desktop computer (PC and Mac), smartphone or tablet. This makes the intervention more accessible and improves engagement. One example is the *Iterapi* purpose-built web-based platform (<https://www.iterapi.se/>), designed at the Department of Behavioural Sciences and Learning at Linköping University, Sweden (Vlaescu, Carlbring, Lunner, and Andersson, 2015; Vlaescu, Alasjö, Miloff, Carlbring, and Andersson, 2016). This platform has undergone continual improvements following experience in providing interventions since 1998 for various difficulties, including auditory-related symptoms. It allows varying levels of access to different aspects of the intervention should be possible by assigning users different roles and privileges. This included what materials, therapeutic contact and discussion forums individuals had access to. Data logging is beneficial to record the frequency of login, modules read, worksheets completed, and the number of messages sent.

Security Considerations

One of the main concerns regarding Internet-interventions is the security of stored personal data. Country specific security regulations need to be followed such as European regulations (Bennett, Bennett, and Griffiths, 2010), the UK Data Protection Act 1998 (UK Parliament, 1998), and The Privacy and Electronic Communications (EC Directive) Regulations of 2003 in the UK (Riach, 2003). These considerations include appropriate technical and organisational measures to safeguard user privacy and confidentiality (Vlaescu et al., 2015; Vlaescu et al., 2016) as outlined below:

- The security of the servers is an imperative consideration to ensure the servers are only accessed by authorised personnel. Multiple backups are required so that data is never lost due to system failure.
- Data storage should be encrypted and the encryption key should only be accessible to two administrators.
- Login should ideally use a two-step process requiring a user code, password and code that is sent to a users' mobile phone. However, a balance between securing data and ensuring login is not too complex, needs to be customised to each intended population. In countries where recipients are familiar with Internet-banking, these processes should be less complex than for countries where users are unaccustomed to these procedures.

- Any intervention related correspondence takes place within the platform so no confidential information is sent unencrypted via email.
- Users need to be informed regarding how collected information may be used and shared. Provided information about Cookie usage and opting out of the programme should be transparent.

A Multidisciplinary Partnership

It is essential to involve a multi-professional team in the process of Internet-based intervention planning. This is particularly important in the context of chronic conditions and symptoms such as tinnitus, which are optimally treated within a multidisciplinary team (Cima et al. 2009). The importance of an experienced webmaster, preferably with expertise in Internet-intervention design and delivery is key. Including a range of professionals ensures that the various aspects of Intervention development are considered. An example of such a team is seen in the development of a UK based Internet-intervention which included clinical psychologists, audiologists, clinical scientists, researchers, a webmaster and a public-patient forum (Beukes et al., 2016).

The Required Infrastructure

Hand-in-hand with this development is ensuring the infrastructure is in place and the associated costs can be supported. Basic requirements include capital costs such as computers, servers and secure storage of these. Employing staff, including a webmaster, those involved in developing and supporting the interventions are, furthermore, required. Ongoing costs such as SSL certificates, Internet connectivity, service maintenance, encryption packages etc. all need to be factored in.

A Strong Theoretical Base

At the heart of intervention design is a secure theoretical base so that the intervention is built on proven conceptual models (Campbell, Fitzpatrick, Haines, and Kinmonth, 2000). The theoretical base of the iCBT self-help programme developed by (Andersson and Kaldø, 2004) combined both a cognitive rationale (Henry and Wilson, 2001) and a learning theory approach (Hallam, Rachman, and Hinchcliffe, 1984) as shown in Table 1. Evidence-based CBT techniques used included negative automatic thought analysis, cognitive restructuring, imagery, applied relaxation, exposure techniques, sleep hygiene and concentration management. Clinically effective audiological principles, such as sound enrichment, hearing tactics and advice for sound sensitivity (e.g. Jastreboff, 2007) were also included. In addition, there were modules based on targeting practical aspects of daily life such as sleep, concentration management and

Table 1. Example modules used in Internet-based cognitive behavioural therapy Interventions

Introduction
● Rationale for the use of cognitive behavioural therapy
● Navigating the website
● Information about tinnitus
● Defining personal goals
● Identifying ways to prioritise spending time on the programme
Tools Provided Within the Intervention
● Applied relaxation
● Positive imagery
● Enhancing focusing
● Exposure to tinnitus
● Sound enrichment
● Reducing sound sensitivity
● Hearing tactics
● Cognitive restructuring
● Sleep management
● Concentration management
Evaluation and Maintenance
● Key point reflection of each intervention tool and evaluation of the effectiveness of each
● Planning how to maintain positive effects
● Relapse prevention planning

future planning. A progressive relaxation programme, together with techniques such as positive imagery, was incorporated to deal with the physical aspects of tinnitus and to promote behavioural change.

To emphasise the theoretical base individual modules should be organised into a clear structure, including an overview, explanation, and rational step-by- step instructions and further help section, covering possible difficulties that may have been experienced.

Providing Support

Internet interventions are either independent of professional support (unguided) or offer some form of support (guided). Guidance is a mechanism whereby individuals can obtain external information about themselves and their progress

(Barak, Klein, and Proudfoot, 2009). Guidance can be synchronous (such as real-time chats), asynchronous (such as emailing) or a blended approach combining various means (Andersson, Carlbring, Ljótsson, and Hedman, 2013). This contact ensures that individuals are supported but require less health professional contact time in comparison to face-to-face interventions (Paxling et al., 2013). The literature consistently shows that guided interventions lead to better outcomes, increased adherence and fewer dropouts, in comparison to unguided programmes (see (Baumeister, Reichler, Munzinger, and Lin, 2014) for a systematic review). Encouragingly, evidence has suggested that therapeutic alliance is important, and that the format thereof (e.g. face-to-face, video, or audio formats) does not lead to substantially different outcomes (Andersson et al., 2012; Day and Schneider, 2002). The Internet-intervention should, therefore, incorporate the flexibility to enable these communication systems. In guided interventions individuals can ask questions about the techniques or difficulties they experience and the health professional can provide further advice, support, motivation, feedback and encouragement as required. To enable appropriate support, the intervention should include notifications to the therapist when individuals have completed worksheets. Feedback can then be provided in a timely manner. A minimum of a weekly check is suggested for reviewing all recipients and providing messages appropriate to the level of engagement.

Overall, to date, evidence indicates that guidance is important and highly rated by individuals undertaking the interventions (Baumeister et al., 2014). Many questions remain regarding the optimal form of this guidance. There is no clear dose-response relationship between support and outcome (Palmqvist, Carlbring, and Andersson, 2007). Furthermore, there is no difference in outcomes when using an experienced or inexperienced therapist (Andersson et al., 2012). Titov et al. (2009; 2010) also found no difference in outcome when guidance was provided by a technician instead of a health professional. It appears as though having the support is the crucial element, rather than who provides the support. In many European based studies providing iCBT, clinical psychologists have provided the support as they are trained in providing CBT. In the UK, tinnitus is largely treated within the audiological community. To follow this approach an audiologist was used to provide iCBT in a UK based study (Beukes, Allen, Manchaiah, Baguley, and Andersson, 2017b; Beukes, Baguley, Allen, Manchaiah, and Andersson, 2017c). As the outcomes were similar to those from previous iCBT interventions using a clinical psychologist for support (e.g. Jasper et al., 2014; Weise, Kleinstaub, and Andersson, 2016) using an audiologist in this context may be a viable option. Further research is required to directly compare outcomes obtained using different forms of guidance.

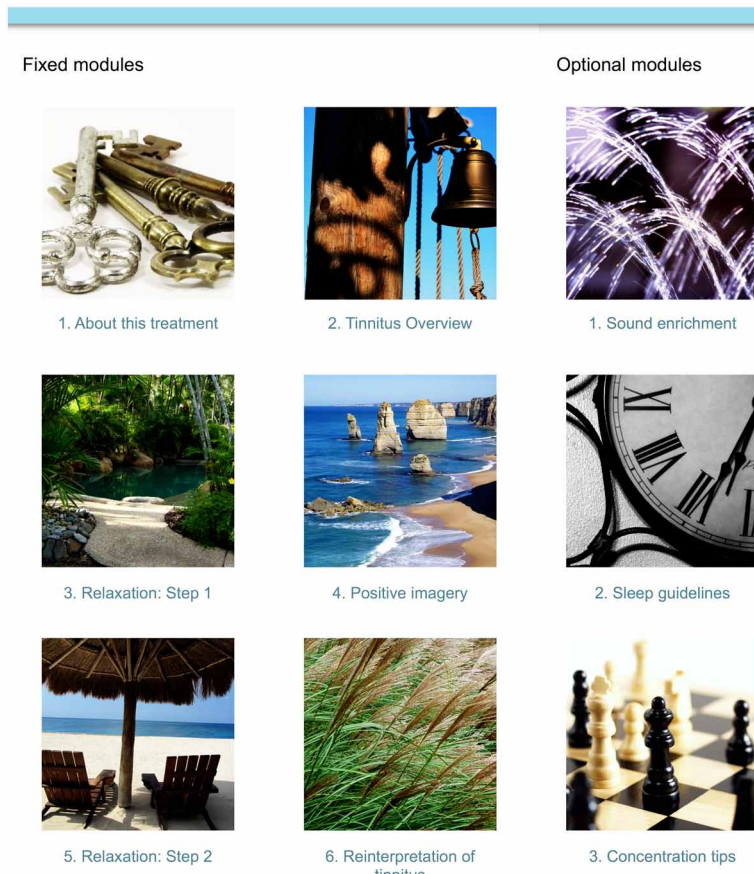
As those with tinnitus often feel isolated, peer support in group therapy can facilitate coping with tinnitus (Thompson, Pryce, and Refaie, 2011). Internet-interventions can include many forms of support. As one example, a discussion forum can, therefore, be included and this forum can be closed (allowing recipients to only read about peer experiences) or open (allowing users to communicate to each other, but moderated by the therapist). An example of a discussion forum topics for an iCBT intervention for tinnitus may be examples of how tinnitus can be reinterpreted, examples of where cognitive restructuring has been applied and how to make relaxation part of daily life.

Tailoring the Intervention

Interventions can be fully standardised or tailored by developing specific aspects based on individual characteristics (Kreuter, Strecher, and Glassman, 1999). This may be personalised communication and/or the ability to select certain therapeutic aspects of the intervention. Providing a tailored intervention aligns the intervention with specific difficulties individuals may be experiencing. Andersson and Kaldo (2004) included tailoring aspects in their tinnitus programme, such as personal treatment goals and receiving individualised weekly feedback. Due to the heterogeneous nature of tinnitus, a tailored intervention, with the flexibility to address individual needs and preferences, is more appropriate than a solely standardised approach. The evidence base supporting this is surprisingly inconclusive. In a meta-analysis reviewing 40 studies, (Lustria et al., 2013) found that tailored interventions resulted in significantly greater improvement in health outcomes compared to non-tailored interventions. On the other hand, Păsărelu, Andersson, Bergman Nordgren, and Dobrea (2017), did not find that tailored interventions lead to improved outcomes in a meta-analysis reviewing 19 Internet-based CBT studies for anxiety and depression. Tailored elements incorporated into Internet-delivered tinnitus programmes developed by Andersson and Kaldo, 2004 included aspects such as personal intervention goals and receiving individualised weekly feedback. The programmes included both optional and compulsory modules thereby acknowledging individual preferences by adapting the intervention according to the specific needs and capacity and by providing a choice of intervention modules according to the symptom profile (Andersson, Estling, Jakobsson, Cuijpers, and Carlbring, 2011). An example of tailoring by letting individual's select optional modules that match their symptom profiles is shown in Figure 1.

A Framework for Designing and Evaluating Internet Interventions

Figure 1. Example of a tailored intervention showing both fixed and optional modules from the tackling tinnitus internet-intervention



Facilitating Participation

The intent of Internet-interventions is to maximise positive outcomes. Active involvement is a key component to deriving intervention benefit (James, 2013). Minimising technological barriers is imperative by ensuring information is straightforward to read and easily accessible. During the development of an Internet-based intervention for tinnitus in the UK, Beukes et al. (2016) facilitated participation by incorporating an interactive approach containing a mixture of information, videos, quizzes, diagrams, suggested techniques to apply to daily life, worksheets to keep track of progress, solutions for common problems and downloadable information. Multifunctional tools were used to address a variety of different learning styles. These tools also provided a means to assess and monitor progress which allowed the health

professional to provide appropriate feedback. To ensure linguistic appropriateness, the Fletcher reading ease (ease of reading on a scale of 0–100) and Flesch-Kincaid Grade Level (the years of education required to understand the writing) of the intervention was assessed. The target was the generally recommended levels of around 60–70 and seven on each scale, respectively (Laplante-Lévesque, Brännström, Andersson, and Lunner, 2012) to ensure that this is not a barrier to participation.

Monitoring Aspects

In addition to the content for users, an Internet-intervention requires a strong administrative element. This should include data logging of the number of times users login, which modules they access, which worksheets are completed, and the number of messages sent. The administrative section is also required to assign roles to users, such as what therapeutic contact they may have and which discussion forums they have access to (Vlaescu et al. 2016).

The ability of the design to monitor progress over time as well as after completion of an intervention is essential. It has been established that collecting outcome measures online does not compromise the psychometric characteristics (Ritter, Lorig, Laurent, and Matthews, 2004; Thoren, Andersson, and Lunner, 2012). Advantages of online data collection include minimising the risk of missing items and that alerts can be provided when red flag questions, such as indicating possible onward referral, are answered. Responses can be verified where required by telephonic interview as a follow-up to the online questionnaire completion. Integrated questionnaires which can be automatically or manually assigned to users, reminders to complete the questionnaires and graphical progress indicators, are useful additional monitoring features.

A FRAMEWORK FOR EVALUATING INTERNET-BASED INTERVENTIONS

Barriers are often encountered during the translation of health-related research into clinical practice and policies (Grol, 2001; Harvey and Kitson, 2015). These barriers lead to discrepancies in evidence-based practice and to the public failing to benefit optimally from advances in healthcare (Grimshaw, Eccles, Lavis, Hill, and Squires, 2012). Tinnitus studies vary in design and there is significant heterogeneity in the evaluation of tinnitus perception and the questionnaires used (Landgrebe et al., 2012). This jeopardises comparison between trials and precludes meta-analysis of intervention effects. The lack of long-term results in addition to the common use of combined approaches in the management of tinnitus are in part responsible for the

lack of conclusive evidence (Landgrebe et al., 2012). It is likely that the differences reported in efficacy and effectiveness of individual Internet-interventions are due to sub-optimal designs during intervention development and evaluation (Morrison et al., 2012). Ensuring that experimental designs include sequential phases of development and evaluation minimise these hurdles (Craig et al., 2008). Suggestions for the evaluation of Internet interventions in a clinical trial format are provided below.

Determining Functionality and Usability of the Intervention

The first step following intervention development is ensuring that no hindrances to its usage exist. In terms of an Internet intervention, the following functionality features should be tested as a minimum:

- Ensuring messages to recipients are delivered and not sent to spam folders is essential. It may be that certain email providers reject emails from providers as a result of certain words used in the messages.
- Checking that recipients are able to login without too much difficulty and providing clear login instructions.
- Testing the navigational aspects, hyperlinks, interactive components, media clips and media links included in the intervention are fully functioning.

In addition, competence associated with computer use can affect engagement with Internet interventions. Cultural differences in the level of computer literacy have previously been reported (Pflug, 2011). Aiming the functionality aspects of the intervention to match the estimated population of cultural computer skills is importance to aid its application.

User Satisfaction and Acceptability of the Intervention

The acceptability of an intervention has always been regarded as one of the key features regarding translating research into practice (Kaltenthaler et al., 2008). Lack of acceptability may influence take-up rates, increase dropout rates and therefore affect the overall effectiveness of an intervention. Acceptability is required by not only individuals undertaking the intervention but also by professionals and non-professionals who have an interest in tinnitus. An effective way is measuring perceived benefit of the actual intervention components in a multidimensional manner. Public patient forums are an ideal channel to enable these evaluations. Beukes et al. (2016) took the approach of letting both tinnitus professionals and users from a tinnitus support group evaluate iCBT adapted for those with tinnitus in the UK. These users were all accustomed to the standard face-to-face tinnitus interventions

provided in the UK, so had this as their point of reference. Both groups highly rated the interventions suitability, content, usability, presentation and monitoring aspects. Open-ended questions were also used to identify which aspects of the intervention required improvement.

Nyenhuis, Zastrutzki, Weise, Jäger, and Kröner-Herwig, (2013) investigated the acceptance of iCBT versus that of group-based face-to-face (F2F) CBT for tinnitus by presenting both groups the same CBT manual material. They found that participants were as satisfied with the iCBT as they were with group-based cognitive behavioural therapy (GCBT) and the dropout attrition was similar, at 35% for both groups. However, more people in the iCBT group did not complete the programme at 64% opposed to 55% for the GCBT. They found that satisfaction was affected by the age of participants, confirming findings by Wise and colleagues (Wise, Rief and Goebel, 1998). Satisfaction with group training increased with age and satisfaction with iCBT decreased with age. Lower levels of initial tinnitus distress were associated with a higher satisfaction for iCBT, a trend not found for the F2F group.

Establishing Intervention Feasibility

Feasibility studies have the purpose of answering the questions regarding whether a study can be done, before the main study is attempted (Eldridge et al., 2016). Establishing the feasibility of a new intervention is crucial prior to more costly and larger scale studies. Various aspects of feasibility may be explored, depending on the nature of the intervention. These are discussed by Thabane et al. (2010) and include:

- Testing the safety of treatment or interventions
- Assessing recruitment potential
- Identifying the standard deviation from the main outcome measure to estimate sample size
- Determining the willingness of participants to be randomised or clinicians to recruit participants
- Retention rates
- Compliance, engagement and adherence rates
- To assess the time and resources required to run the trial
- To determine whether the eligibility criteria is sufficient or too restrictive

Attrition rates are often a concern of any intervention including iCBT, with varying ranges reported such as 57% by Abbott et al., (2009) versus 5% by Hesser et al. (2011). Initial feasibility studies can help assess attrition rates and adjust protocols to reduce these if required. As iCBT for tinnitus has not been used in the UK before, Beukes et al. (2017b) ran a feasibility study to identify the recruitment potential,

retention rates and intervention engagement. In comparison to the recruitment rates in Sweden, the initial take-up rates in the United Kingdom were low and the target population was not reached. This identified that the recruitment strategy was not optimal and strategies were put in place to improve recruitment for subsequent trials. Some participants struggled to engage with the iCBT intervention and the barriers identified included time constraints, work pressures, and poor health.

Kaldo et al. (2008) found that 43% of participants did not complete the full iCBT programme, but explained that this was similar when compared to the number of sessions actually attended by those receiving group-based CBT. Possible reasons have been attributed to (a) a higher intrinsic motivation for those that valued task completion (Donkin and Glozier, 2012), (b) were actively involved and (c) had a positive attitude and hope (Heinrich et al., 2016). By investigating such feasibility issues, they can be addressed before larger scale studies.

Piloting the Intervention

A pilot study is a smaller version study, resembling the design of a further larger scale trial (Eldridge et al., 2016). The importance of running a full pilot study as a proof-of-concept evaluation is often underestimated and omitted. It can assist with preparing and planning larger scaled investigations by examining the reliability and validity of the proposed study design (Thabane et al., 2010). The aim of a pilot study is not to evaluate a treatment effect, but rather to identify shortcomings in both the intervention and the protocol and can help to facilitate the smooth running of subsequent larger trials (Thabane et al., 2010). Pilot studies ensure that efficacy testing has the best chance of success by troubleshooting potential issues early on. They can increase the clinical experience of running a new intervention, generate data for sample size calculations and refine the inclusion and exclusion criteria. They can assess the time required to complete questionnaires and to do the intervention. Pilot studies have different objectives to the main trial and should include an intention for future work.

Assessing Intervention Efficacy

Determining the efficacy of an intervention is an important step during intervention evaluation. The design selected is crucial to ensure sound methodological principles are incorporated and bias is minimised. Efficacy trials prioritise internal validity and therefore include a control group in the study design. They evaluate whether an intervention can work under ideal circumstances (Cochrane, 1972). The use of randomised clinical trials (RCT) is a central component in evaluating new interventions. Participants are randomised into groups with the aim of obtaining

an unbiased and reliable comparison these groups. Randomisation is important as it ensures that participants are objectively similar regarding demographic and prognostic factors in the selected groups. Randomisation achieves this as each participant has a known chance of being given the intervention in an allocation that cannot be predicted (Altman and Bland, 1999). Masking participants and researchers to group allocation where possible should be incorporated, as this removes any systematic bias there may be during the assessment and allocation during the trial conduct. To ensure that rigorous methods are selected, the Consolidated Standards of Reporting Trials (CONSORT) guidelines should be followed (Schulz, Altman, and Moher, 2010). These guidelines set standards to adhere to such as ensuring the trial will have enough power to produce statistically valid results.

The assessment measures selected to measure outcome need careful consideration to ensure they are appropriate for the study design. Self-reported assessment measures are generally used in clinical practice to quantify tinnitus distress and identify associated difficulties that may be present. An Internet intervention design has the advantage of enabling data collection of these assessment measures online. This reduces the administrative requirements associated with using hard copies. Algorithms can be used to automatically score responses and results can be easily exported.

Selecting assessment measures that have been psychometrically validated and match the trial design is important. The primary outcome of a tinnitus intervention would be a reduction in tinnitus-related distress after undergoing the intervention. It is of value to know if the intervention is effective at reducing any associated effects. Secondary outcomes may involve tinnitus-related difficulties such as insomnia, anxiety and depression (Hall et al., 2018). As an example Beukes et al. (2017c) included measures for insomnia, anxiety, depression, hyperacusis, hearing disability, cognitive failures, and life satisfaction.

Results of efficacy trials to date have indicated promise that iCBT for tinnitus can reduce tinnitus distress and many of the associated comorbidities as shown in Table 2. The results of early trials had small effect sizes, whereas later trials indicated medium to large effect sizes (by overcoming methodological shortcomings of some of the earlier trials).

Can Intervention Effects Be Maintained?

Evidence that intervention effects are maintained over time is important, especially when outlining the benefits of a new intervention. Measuring the stability of intervention effects at least 1 year post intervention is therefore important. It may be a challenge to obtain results at this time frame, and strategies need to be sought to encourage completion of assessment measures such as telephoning individuals prior to these assessments. Studies have evaluated the results of iCBT up to 1 year

Table 2. Results from iCBT efficacy trials using passive and active controls

Study	Country	Groups	Between group effect size for tinnitus distress post-intervention	Assessment Measures
Andersson, Strömberg, Ström, & Lyttkens, (2002)	Sweden	1. iCBT: n = 26 2. WLC: n = 64 who later undertook the intervention	$d = 0.27$	<ul style="list-style-type: none"> • Tinnitus distress • Anxiety • Depression • Insomnia
Kaldo et al. (2008)	Sweden	1. iCBT (n = 25) 2. GCBT (n = 26)	1. $d = 0.73$ 2. $d = 0.64$	<ul style="list-style-type: none"> • Anxiety • Depression • Insomnia • Visual analogue scales for tinnitus loudness, distress and perceived stress
Abbott et al. (2009)	Australia	1. iCBT: n = 32 2. Information only control (IOC): n = 24	$d = 0.25$	<ul style="list-style-type: none"> • Tinnitus distress • Depression
Hesser et al. (2011)	Sweden	1. iCBT: n = 32 [shorter text of 157 pages divided into 8 modules] 2. Internet based acceptance and commitment therapy (iACT): n = 35 [104 pages] 3. A discussion forum group control (DFC): n = 32	$d = 0.70$ for iCBT versus the control	<ul style="list-style-type: none"> • Tinnitus distress • Tinnitus acceptance • Anxiety • Depression • Quality of life • Perceived stress
Nyenhuis et al. (2013)	Germany	1. iCBT self-management (n=79) 2. CBT bibliotherapy (n = 77) 3. GCBT (n =71) 4. Information-only control (n = 77)	$d = 0.57$ for iCBT versus the control	<ul style="list-style-type: none"> • Tinnitus distress • Depression
Jasper et al. (2014)	Germany	1. iCBT (n = 41) 2. GCBT (n = 43) Internet-based discussion forum control (n = 44)	1. $d = 0.56$ for iCBT versus the control	<ul style="list-style-type: none"> • Tinnitus distress • Depression • Insomnia
Weise et al. (2016)	Germany	1. iCBT (n = 25) 2. GCBT (n = 26)	$d = 0.84$	<ul style="list-style-type: none"> • Tinnitus distress • Tinnitus • Acceptance • Depression • Anxiety insomnia
Beukes et al., (2017c)	UK	1. iCBT (n=73) 2. A weekly check in control (n=73)	$d = 0.69$	<ul style="list-style-type: none"> • Tinnitus distress • Anxiety • Depression • Insomnia • Hyperacusis • Hearing Disability • Cognitive failures • Satisfaction with life

post-intervention and have found maintenance of intervention effects. Three of these long-term studies have been in Sweden (Andersson et al., 2002; Kaldø et al. 2008; and Hesser et al. 2011), one in Germany (Weise et al., 2016) and a further one in the UK (Beukes, Allen, Bagüey, Manchaiah, and Andersson, 2018a). Further exploration of intervention effects for 2 and 3 years post intervention is required.

Establishing Intervention Effectiveness in Regular Clinical Settings

It is not always clear whether results from efficacy studies can be generalised into normal clinical practice. A limitation of efficacy research is that intervention effects are not contextualised as they are not applicable in typical intervention settings (Glasgow, Lichtenstein, and Marcus, 2003). As a follow-up from these, effectiveness studies examine whether the intervention is effective in real-world clinical settings and in situations that health professions encounter in their daily routine practice (Lutz, 2003). This type of study emphasises the external validity of the research findings.

Effectiveness studies can take various forms. Some compare new interventions to the usual clinical care which is regarded as the gold standard of evaluating new interventions. The aim is generally to show that a new intervention is not inferior when compared to an existing intervention. Consort guidelines should be followed when running non-inferiority and equivalence randomised trials (Piaggio et al., 2012).

Internet interventions delivered in regular clinical services for a range of conditions and symptoms, consistently show sustained effects with moderate to large effect sizes (Andersson and Hedman, 2013). Previous trials comparing iCBT to the usual tinnitus care are summarised in Table 3.

There have been two Swedish studies looking at iCBT for tinnitus in a regular clinical setting (Uppsala Hospital in Sweden), using clinical psychologists and not using advertisements to recruit participants. The first was an open effectiveness trial by Kaldø-Sandström, Larsen, and Andersson (2004) using 77 participants. The within group effect size was Cohen's $d = 0.56$. The second offered two parallel interventions, namely, iCBT ($n = 293$) and a low-intensity version of iCBT ($n = 81$) aimed at those with lower tinnitus distress (Kaldø et al., 2013). Results indicated a reduction in tinnitus distress (Cohen's $d = 0.58$), depression, anxiety, and insomnia for those undertaking the full iCBT intervention. Those undertaking the low-intensity version also showed a reduction in tinnitus, although effect sizes were smaller. This may have been related to a lower baseline tinnitus distress levels. The authors concluded that guided iCBT could be successfully used in a regular clinical setting to reduce tinnitus distress. As iCBT has not to date been compared to individualised therapy, Beukes and colleagues (2018) compared iCBT to usual individuated tinnitus therapy

Table 3. Results comparing iCBT to usual clinical care

Study	Location	Groups	Within group effect size
Kaldo-Sandström, Larsen & Andersson (2004)	Sweden	iCBT (n = 77) not randomized from CBT waiting list	<i>Within group effect size for the iCBT group: $d = 0.66$</i>
Kaldo et al. (2013)	Sweden	1. iCBT (n = 293) 2. Low intensity iCBT (n = 81) Not randomised	<i>Within group effect size for the iCBT group: $d = 0.58$ Low intensity group: $d = 0.26$</i>
Beukes et al. (2018)	United Kingdom	3. iCBT (n = 46) 4. F2F individualised tinnitus care (n = 46)	<i>Between group effect size: $d = 0.32$ Within-group iCBT effect size $d = 1.28$</i>

Acronyms: F2F: Face-to-Face; GCBT: Group-based cognitive behavioural therapy; iCBT: Internet-based cognitive behavioural therapy

in England in a non-inferiority randomised control trial and found that results from both interventions were comparable.

IMPLEMENTATION

Implementation of new interventions is complex and may require adaptation of settings and service systems (Andrews and Williams, 2015). Some aspects of guided Internet-Intervention make implementation easier than face-to-face therapies. These include having a highly structured and scripted nature, leaving less room for therapist drift. Outcome monitoring is also embedded in the implementation, thus facilitating the assessment of progress and safety. Rolling out implementation in different settings is also less complex due to the reduced need to duplicate resources, as the same intervention can be used in a centralised manner (Andersson and Titov, 2014). Strategies to aid implementation are discussed in the sections that follow.

Process Evaluation

Presenting the results of assessment outcomes alone do not provide enough information to determine whether new interventions work. A more holistic approach is required to interpret the results and identify factors that facilitate and hamper the application of interventions (Saunders, Evans, and Joshi, 2005). Process evaluation is a means of uncovering various aspects related to implementation and delivery of interventions over time (Manchaiah, Danermark, Ronnberg, and Lunner, 2014). This includes

indicating the research context, factors that contribute to positive outcomes and how interventions can be optimised (Moore et al., 2015). Process evaluation provides the opportunity to collect both quantitative and qualitative information that can provide a holistic view of any intervention effects. These models can be used to provide a framework for evaluating an intervention's potential for successful implementation. The models that have been widely used in healthcare interventions include those of Baranowski and Stables (2000) that suggest 11 components, and the Reach, Efficacy, Adoption, Implementation and Maintenance framework (RE-AIM; (Glasgow, Vogt, and Boles, 1999)). These models give balanced attention to both internal and external validity elements of research design and evaluation and can be used to estimate the potential public health impact of interventions.

Despite the relevance of process evaluation, there has only been one comprehensive process evaluation to date investigating factors that facilitate or hinder implementation of iCBT for tinnitus (Beukes, Manchaiah, Baguley, Allen, and Andersson, 2017). The parameters they chose are shown in Table 4. Performing a process evaluation indicated barriers that would need to be addressed prior to implementing this intervention. These included improving engagement and motivation, which was found to be variable and encouraging intervention take-up in groups least likely to undertake the intervention such as young adults and those in remote areas.

Establishing Cost-Effectiveness

Where possible cost-effectiveness should be established together with clinical effectiveness in order to be useful for decision makers/budget holders. To date, this aspect has been rarely evaluated (Kaldo et al., 2008) reported that iCBT for tinnitus was 1.7 times more time-effective than seven sessions of group-based CBT in Sweden whereas Beukes and colleagues (2018) found iCBT 2.7 times as time-effective compared with individualised tinnitus care. A lexicon of assessment and outcome measures for tele-mental health has been developed as a resource for the evaluation of these services (Shore et al., 2014). Evaluation metrics include treatment utilisation, travel costs, stigma, anxiety, waiting times, training, and motivational readiness. Future research can use these domains to standardise approaches, to determine cost effectiveness and provide a more comprehensive comparison of services.

Key Strategies to Aid Implementation

There are some key strategies to help new intervention translation into routine practice as suggested by Craig et al. (2008). Implementation of new interventions is dependent

Table 4. Process evaluation parameters used by (Beukes et al., 2017)

Process	Description	Assessment measure
<i>Processes related to the research context</i>		
<i>Recruitment</i>	Procedures used to approach and attract participants	Monitoring traffic on the recruitment website via Google analytics
<i>Reach</i>	The extent to which the intervention was received by the targeted population of those with distressing tinnitus who were underserved with previous interventions for tinnitus	Demographic questionnaire
<i>Context</i>	The social, demographic and socio-economic characteristic of the participants that may affect generalisability of the outcomes	Demographic questionnaire and baseline levels on assessment measures
<i>Processes related to the intervention delivery</i>		
<i>Treatment (dose) delivered</i>	Intervention components actually provided to participants	Nature of the guided-intervention
<i>Treatment (dose) received</i>	The extent to which participants engaged in and adhered to the intervention	Data logging
<i>Processes related to the outcomes obtained</i>		
<i>Barriers affecting the outcomes obtained</i>	Barriers that may affect the outcomes obtained	Post-intervention satisfaction questionnaire
<i>Factors facilitating effectiveness</i>	Intervention's effectiveness from the participant's perspective	A benefit questionnaire was used to rate the iCBT modules

on removing known barriers that are likely to prevent implementation. These may include legal, confidentiality, data-security, cost, acceptance and operational barriers (Hill and Powell, 2009).

In addition, intervention credibility is required. Acceptance of new interventions is largely based on health professionals' attitude toward them (Perle et al., 2013). Much work is still required to improve attitudes towards Internet-interventions from both the perspectives of patients and healthcare professionals (Eikelboom, 2016). Unfounded fears, such as concerns that clinical intervention routes will no longer be required need to be addressed. Additional management routes are required to complement existing interventions as many people are unable to access tinnitus interventions at present. Approaching these fears in a culturally sensitive manner is important (Hadjistavropoulos, Thompson, Klein, and Austin, 2012).

Patient's perception of Internet interventions is also important. Musiat, Goldstone, and Tarrrier (2014) found that perceptions in the UK of computerised interventions were poor and a greater acceptance was found for face-to-face interventions. In Europe, variable results have been found. Kaldo et al. (2008) compared intervention credibility ratings for those experiencing significant tinnitus. They found that group CBT was rated more credible than iCBT. On the other hand, Kaldo-Sandström et al. (2004) did not find a difference in credibility rating between iCBT and group-based CBT. Much work is still required in this area before Internet-interventions are viewed as credible interventions by patients, health professionals and stakeholders alike.

SOLUTIONS AND RECOMMENDATIONS

This chapter has outlined the potential for Internet-Interventions to improve healthcare for tinnitus. The ultimate health-care goal would be to help implement innovative interventions that demonstrate benefits into clinical practice. In reality there is poor translation of these research findings into practice due to the challenging and multifaceted processes required. This chapter aims to improve rates of success by providing a framework to assist in the design of evidence-based effective interventions that have been appropriately evaluated.

Effectiveness studies are required as a minimum to ensure the intervention works in practice, can be delivered in the intended setting, and be cost effective. Prior to implementation, it is recommended that two efficacy and two effectiveness trials are performed to ensure the intervention can be delivered in the intended settings and within the proposed budget (Tomlinson, Rotheram-Borus, Swartz, and Tsai, 2013)

In terms of Internet interventions for tinnitus, these should be regarded as a complement to other services and by no means a replacement for face-to-face therapies which are beneficial particularly to those with complex needs and those unable to use the Internet. The aim would be to run tele-audiology services in parallel to other currently provided tinnitus interventions.

A key strategy of implementation is involving stakeholders from the inception in the choice of research design to identify elements relevant to decision-making, such as benefits, harms, and costs. Outlining the intended intervention effects are also required. In addition ensuring health professionals are positive about implementing these services is important.

Interventions will also require tailoring according to the specific implementation context. Strategies to ensure continued evaluation and monitoring need to be in place (Andrews and Williams, 2015). These innovations require dedicated practitioners to integrate forms of tele-audiology into healthcare using innovative solutions.

FUTURE RESEARCH DIRECTIONS

There are numerous future research themes still required before Internet-interventions can be integrated into clinical care. One is to identify for whom these Internet interventions are most suitable. To date, there are no established predictors for outcomes of guided iCBT (Andersson and Hedman, 2013).

Although support within Internet interventions both from health professionals and peers with tinnitus is important, the optimal way to provide support requires further attention. The degree and form of guidance required still needs to be established. Factors aiding implementation of Internet-based interventions will also strengthen implementation of new interventions. One challenge is keeping up with the dynamic nature of the field by continually updating these interventions according to advances in the research. Perhaps the greatest research challenge is identifying factors that can aid acceptability and credibility of these interventions by health professionals and stakeholders. It is also important to ensure that end-users value these services and are satisfied with what they offer.

CONCLUSION

Much potential exists for tele-audiology. One form of tele-audiology, namely an Internet-based intervention for tinnitus has been discussed. The process from development to implementation is outlined and a framework is provided that can be used by those interested in further developing tele-audiology, an area filled with potential.

ACKNOWLEDGMENT

We are grateful to the British Society of Audiology for funding the effectiveness trial in the UK. We would like to thank Linköping University, Anglia Ruskin University, Lamar University and the University of Nottingham for supporting work related developing Internet-Interventions for Tinnitus. We thank George Vlaescu for his expertise in web design and technical support.

DISCLAIMER

The involvement of the authors was supported by their institutions, Anglia Ruskin University, Lamar University, Linköping University, National Institute of Health Research, but the views expressed are made by the authors and do not represent those of these institutions nor the UK Department of Health. These organisations had no role in the approval or preparation of this chapter.

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KEY TERMS AND DEFINITIONS

Cognitive Behavioral Therapy (CBT): A form of psychological therapy that is directed at modifying unhelpful thought patterns and behaviors to help manage specific problems.

Digital Healthcare: Providing healthcare in formats other than face-to-face contact, such as internet and computer-based interventions.

E-Health: Utilization of information and communication technologies to deliver healthcare.

Guided Intervention: Real-time or asynchronous professional support while undertaking an intervention.

Habituation: Becoming accustomed to perceiving tinnitus to the point that it does not affect day-to-day functioning and has no associated negative emotional response.

Internet-Based Cognitive Behavioral Therapy (iCBT): Cognitive behavioral therapy provided via the internet.

Internet Intervention: Using the internet as means of delivering healthcare.

Tailored Intervention: Interventions that include aspects such as personalized messages or content that can be adapted for an individual.

Tinnitus: The perception of a sound in the absence of an identifiable external sound source.

Usual Face-to-Face (F2F) Tinnitus Care: Receiving individual or group-based care in a clinic from a hearing-care practitioner.